United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

OCT 9 2003

Dr. Birgitte Povlsen, Head Senior Veterinary Officer
Director Food Control Department
Danish Veterinary and Food Administration
Moerkhoel Bygad 19
DK – 2860 Soeborg
DENMARK

Dear Dr. Povlsen:

Enclosed is a copy of the final report of the Food Safety and Inspection Service (FSIS) audit of Denmark's meat inspection system conducted from January 9, 2003 through February 11, 2003. Comments by Denmark on the draft final audit report have been included as Attachment "G" in the final audit report.

If you have any questions or need additional information, please contact me by telephone at (202) 720-3781. You may also contact me by fax at (202) 690-4040 or by e-mail at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen

Sally Stratmoen, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:
Roger Wentzel, Agricultural Counselor, American Embassy, The Hague
Vibeke Faurby, 1st Secretary, Minister Counselor, Royal Danish Embassy
Agriculture, Fisheries, Food Safety and Consumer Affairs Section , EU, DC
Scott Bleggi, FAS Area Officer
Dave Young, ITP, FAS
Linda Swacina, Deputy Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA, FSIS
Amy Winton, State Department
Donald Smart, Director, OPEER, FSIS
Clark Danford, Director, IEPS, OIA
Sally Stratmoen, Director, IES, OIA
Richard F. Brown, IES, OIA
Steve McDermott, IES, OIA
Country File (Denmark FY 2003 Audit)

FINAL

SEP - 8 2003

FINAL REPORT OF AN AUDIT CARRIED OUT IN DENMARK COVERING DENMARK'S MEAT AND POULTRY AND EGG PRODUCTS INSPECTION SYSTEM

January 9 through February 11, 2003

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Danish Veterinary Food Administration)
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction / Hazard Analysis and Critical Control Point
Salmonella	*Salmonella* species
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Denmark from January 9 to February 11, 2003.

An opening meeting was held on January 9, 2003 in Copenhagen with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of the Danish meat inspection system. General information about the Danish Veterinary Food Administration, animal disease status and itinerary were provided to the auditor.

The auditor was accompanied during the entire audit by representatives from the CCA, the Danish Veterinary Food Agency, and representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, three regional inspection offices, two laboratories performing analytical testing on United States-destined product, two cattle and two swine slaughter establishments, six cold stores and three meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	3	Interviewed 3 chief Vets.
Laboratories		2	
Meat Slaughter Establishments		4	
Meat Processing Establishments		3	
Cold Storage Facilities		6	

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to 13 establishments: four slaughter establishments, three processing establishments and six cold storage facilities. The third part involved visits to one government and one private laboratory. The Food Region

Northern Jutland Microbiology Laboratory was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species. The Food Region Ringsted Residue Laboratory was conducting analyses of field samples for Denmark's national residue control program.

Program effectiveness determinations of Denmark's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and the testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including the testing program for *Salmonella* species. Denmark's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Denmark and also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella* species.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Denmark under provisions of the Sanitary/Phytosanitary Agreement. For *E. coli* and *Salmonella* equivalence determination see Sections 11.3 and 13.2 respectively.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).

- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- Council Directive 96/23/EC, of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"
- Council Directive 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists"

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofo/tsc.

The last two audits of Denmark inspection system have shown serious problems.

Of the problems identified in April 2001, the following had been corrected by the audit in February 2002:

- Pre-shipment document reviews had not been developed and implemented in 10 of 25 establishments. *This had been resolved.*

- Additional sanitizers were required in essential locations in two of nine establishments.
  This had been resolved.

- Condensation controls were inadequate in two establishments. *This had been resolved.*

Of the problems identified in April 2001, the following had not been corrected by the February 2002 audit:

- *Maintenance and cleaning of over-product equipment had been neglected in four of the nine establishments visited.* Similar problems were found in four of the 11 establishments.

- *Light was inadequate in the retained carcass inspection areas in two establishments.* Light was again found to be inadequate in two establishments.

- *Documentation of Sanitation Standard Operating Procedures was inadequate in two establishments.* Problems were again identified, but in only one establishment.

The following additional concerns were identified during the February 2002 audit:

- Visible fecal contamination was found on product that had passed all establishment and DVFA inspection controls in two of the 11 establishments audited on-site. Also,

in these two establishments, the written controls for enforcement of the zero-tolerance policy for visible fecal contamination were not followed as required.

- During the year prior to this audit, supervisory internal reviews were not consistently conducted monthly.

- Inadequate cleaning of product-contact equipment before use was found in three of the seven establishments in which exposed product was handled.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Denmark legislation.

6.2 Government Oversight

6.2.1 CCA Control Systems

The Danish Ministry for Food, Agriculture, and Fisheries was divided into four departments, including the Food and Environment Department (FED). Within FED was the Veterinary and Foodstuffs section, which contained the Danish Veterinary and Food Administration. Within DVFA were the Danish Veterinary Service, the Food Control Department Administration, and the Danish Veterinary Laboratory/Institute. Also within DVFA, and directly under the control of the Director General for DVFA, were the 11 Regional Veterinary and Food Control Authorities (RVFCAs). In general, the 11 Regional Authorities had the same four departments. Within the Food Control Department of each RVFCA were the Chief Veterinarians, who served as field supervisors over the resident veterinarians and inspectors within one or more certified establishments.

6.2.2. Ultimate Control and Supervision

The CCA must have ultimate control and supervision over official activities of all employees and certified establishments.

- One establishment was decertified during this audit.
- Two establishments required a 30-day notice from the CCA.

6.2.3 Assignment of Competent, Qualified Inspectors

The CCA must ensure the assignment of competent and qualified inspectors.

- Supervision of inspectors in the certified establishments needs to be improved. At three establishments there were deficiencies in inspection controls.

- The EC Directive 64/433 implementation deficiencies were observed in the categories of establishment grounds and pest control, establishment construction/maintenance, light, ventilation, plumbing and sewage, dressing and room/lavatories, equipment and utensils, sanitary operations, and employee hygiene.

6.2.4. Authority and Responsibility to Enforce the Laws

The CCA must have authority and responsibility to enforce U.S. requirements and must exercise that authority.

- In one establishment, zero tolerance for fecal contamination was not enforced.

6.2.5 Adequate Administrative and Technical Support

The CCA must have adequate administrative and technical support to operate the country's inspection system.

- No problems were observed.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the regional office. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result of the examination of these documents.

6.3.1 Audit of Regional and Local Inspection Sites

No concerns arose as a result of the audit of Regional and Local Inspection offices. There was proper level of oversight under; management structure, independence and resources, recruitment and training, prioritization of controls and documentation of controls.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 13 establishments—four slaughter establishments, three processing establishments, and six cold storage facilities. One establishment was delisted by Danish Veterinary Food Administration because of zero-tolerance violation for fecal contamination, improper *E. coli* testing documentation and HACCP deficiencies. Two establishments received "30-day notices" (notification in writing that corrective actions must be implemented within 30 days) from Denmark because of SSOP, Sanitation, and HACCP deficiencies. These establishments may retain their certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratories were audited:

The Government Food Region Ringsted Residue Laboratory was audited on January 24, 2003. The Government Food Region Northern Jutland Microbiology Laboratory was audited on January 21, 2003.

The findings in these laboratories will be discussed in Section 11.3 (Testing for generic *E. coli*), Section 12 (RESIDUE CONTROLS), OR Section 13.2 (Testing for *Salmonella* species) of this report.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviews is Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Denmark's inspection system had controls in place for product storage practices.

In addition, and except as noted below, Denmark's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, welfare facilities, and outside premises.

The following deficiencies were observed:

- establishment grounds and pest control
- establishment construction/maintenance
- light
- ventilation
- plumbing and sewage
- dressing room/lavatories
- equipment and utensils
- sanitary operations
- employee hygiene

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP program in the eight establishments were found to meet the basic FSIS regulatory requirements with the following deficiencies:

- implementation of SSOP
- maintenance and evaluation of the effectiveness of SSOP
- corrective action and daily records

9.2 EC Directive 64/433

In six establishments, the provisions of EC Directive 64/433 were effectively implemented. In the seven establishments with deficiencies, the specific deficiencies are noted in the applicable sections and sub-sections of this report and in the attached individual establishment checklists.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviews is Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that the Danish inspection system had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviews is Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the seven establishments. Four establishments had adequately implemented the PR/HACCP requirements.

- Three establishments had HACCP implementation deficiencies; one of them had repeat deficiencies. The inspection officials took corrective action. In one of these three establishments, the basic HACCP requirements were not met.

Deficiencies observed in three establishments included:

- critical limits
- monitoring activities
- corrective action and verification

These categories were not properly described in one establishment under basic requirements. Monitoring, corrective action and verification were not implemented.

11.3 Testing for Generic *E. coli*

Denmark has adopted the FSIS regulatory requirements for generic E. coli testing with the exception of the following different equivalent requirements:

1. Sampling tools.

    - Denmark uses a gauze swab sampling tool. The gauze swab is a generally/internationally recognized sample collection tool for *E. coli* on meat or poultry product surfaces.

    - The sampling tool is sensitive enough to gather *E. coli* that are present at the sample sites.

    - The sampling tool does not contaminate the surface of the carcass.

2. Analytical methods (Different methods).

    - Denmark uses an NMKL method to analyze for generic *E. coli*. This method is a quantitative method of analysis.

    - The method is approved by the AOAC International or an internationally recognized scientific organization.

Four of the 13 establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in three of the four slaughter establishments.

- In one establishment a statistical process control to evaluate the results of testing for generic *E. coli* had still not been properly implemented and documented.

11.4 Testing for *Listeria Monocytogenes*

Testing for *Listeria monocytogenes* is performed where required.

11.5 EC Directive 64/433

In six establishments, the provisions of EC Directive 64/433 were effectively implemented.

11.6 Ante and Post Mortem Inspection

- Unified synchronization of inspected carcasses needs improvement in one establishment
- Extremely dirty animals received on ante-mortem inspection

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviews is Residue Controls. At the government residue laboratory that was audited, sample procedures, analytical procedures, and Quality Assurance procedures were evaluated. These procedures covered areas of sample handling, sampling frequency, timely analyses, compositing procedures, interpretation of compositing data, data reporting, acceptable method, correct tissues, equipment operation, instrument printouts, minimum detection level, recovery frequency, percent recovery, check sample frequency, analysts with check samples, corrective actions and international check samples.

The Government Food Region Ringsted Residue Laboratory was visited on January 24, 2003. No deficiencies were noted.

Denmark's National Residue Control Program for 2003 was being followed and was on schedule.

12.1 FSIS Requirements were being followed.

12.2 EC Directive 96/22

In the Food Region Ringsted Residue Laboratory, the provisions of EC Directive 96/22 were effectively implemented

12.3 EC Directive 96/23

In the Food Region Ringsted Residue Laboratory, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviews is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

13.2 Testing for *Salmonella*

Denmark has adopted the FSIS regulatory requirements for HACCP. *Salmonella* testing is the same with exception of the following equivalence measures:

1. Sample collector: Establishments take samples.

- The government of Denmark provides a clearly written sampling plan with instruction for sample collection and processing that is followed by all applicable export establishments.

- All applicable veterinarians are properly and uniformly trained. The veterinarians train the establishment employees. The trained veterinarian will observe the collection/storage/transport procedures on a periodic, unannounced basis to ensure that FSIS requirements are met. The government ensures that establishment sample collection activities are appropriate. Sample verification is performed once every week by the DVFA where the official veterinarian collects samples and the DVFA analyzes the sample.

- The government of Denmark uses the test results to monitor establishment performance over time.

- The government of Denmark takes immediate action any time an establishment fails to meet a *Salmonella* performance standard.

2. Laboratories. Private laboratories analyze samples.

    - The laboratories are independent non-government or establishment laboratories that are all accredited by the government of Denmark. The laboratories are required to participate in performance testing to ensure laboratory analyzes are properly performed. Establishment labs are under the direct supervision of the on-site veterinarian.

    - All accredited laboratories have a formal program to ensure that lab personnel are properly trained, that there are suitable facilities and equipment, that there is a written quality assurance program, and that there are adequate reporting and record keeping facilities.

    - Test results are provided directly to the government veterinarian.

3. *Salmonella* testing strategy

    - Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. The sampling methodology is based on a uniform system approach in all applicable export establishments. All U.S. export establishments are included in the sample pool. Denmark collects one sample per production day, grouped in sample sets of 55 samples (swine) and uses FSIS Performance Standards and enforcement procedures.

    - Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is a U.S. performance standard are included in the sample pool.

- Denmark's testing program has statistical criteria for evaluating test results.

- The percentage of *Salmonella* positives over time meets the FSIS percentage of positives in the FSIS standard.

3. Sampling tools.

    - The gauze pad sampling tool is used. This sampling tool is internationally recognized for sampling *Salmonella* on meat or poultry product surfaces.

    - The sampling tool is sensitive enough to gather *Salmonella* that are present at the sample sites.

    - The sampling tool does not contaminate the surfaces of the carcass.

Four of the 13 establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic program. Testing for *Salmonella* species was properly conducted in all four establishments.

13.3 Species Verification

At the time of this audit, Denmark was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

No livestock or meat was imported from third countries for product eligible for export to the United States.

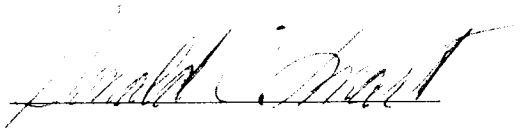
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on February 11, 2003 in Copenhagen with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Oto Urban
International Audit Staff Officer



15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Laboratory Review Reports
Foreign Country Response to Draft Final Audit Report

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

REVIEW DATE: 1-21-03

NAME OF FOREIGN LABORATORY: Government Food Region Northern Jutland Laboratory

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Danish Veterinary and Food Administration	Aalborg, Denmark	Sofiendalsvej 90, 9200 Aalborg SV

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Oto Urban	Dr. Ole A. Kyvsgard

	REVIEW ITEMS	ITEM #	EVALUATION CODE	Residue Code/Name ▶ Sal	E.co
SAMPLING PROCEDURES	Sample Handling	01		A	A
	Sampling Frequency	02		A	A
	Timely Analyses	03		A	A
	Compositing Procedure	04		O	O
	Interpret Comp Data	05		O	O
	Data Reporting	06		A	A
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A
	Correct Tissue(s)	08		A	A
	Equipment Operation	09		O	O
	Instrument Printouts	10		O	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	O	O
	Recovery Frequency	12		O	O
	Percent Recovery	13		O	O
	Check Sample Frequency	14		A	A
	All analyst w/Check Samples	15		A	A
	Corrective Actions	16		A	A
	International Check Samples	17		A	A
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O
OTHER REVIEW		19	EVAL. CODE		
		20			

SIGNATURE OF REVIEWER: Oto Urban

DATE: 1/21/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE	NAME OF FOREIGN LABORATORY
1-21-03	Government Food Region Northern Jutland Laboratory

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Danish Veterinary and Food Administration	Aalborg, Denmark	Sofiendalsvej 90, 9200 Aalborg SV

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Oto Urban	Dr. Ole A. Kyvsgard

RESIDUE	ITEM	COMMENTS

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 1-24-03

NAME OF FOREIGN LABORATORY: Government Food Region Ringsted Residue Laboratory

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Danish Veterinary and Food Administration	Ringssted, Denmark	Sondervang 4 . DK-4100 Ringsted

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Oto Urban	Dr. Arne Kongsted, M.Sc Inga Orntoft

	Residue Code/Name ▶		100	111	200	203	300	400	500	800	SP			
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01		A	A	A	A	A	A	A	A	A		
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A		
	Timely Analyses	03		A	A	A	A	A	A	A	A	A		
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O		
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O		
	Data Reporting	06		A	A	A	A	A	A	A	A	A		
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A	A	A		
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	A		
	Equipment Operation	09		A	A	A	A	A	A	A	A	A		
	Instrument Printouts	10		A	A	A	A	A	A	A	A	A		
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	A	O		
	Recovery Frequency	12		A	A	A	A	A	A	A	A	O		
	Percent Recovery	13		A	A	A	A	A	A	A	A	O		
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A		
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A	A		
	Corrective Actions	16		A	A	A	A	A	A	A	A	A		
	International Check Samples	17		A	A	A	A	A	A	A	A	A		
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O	O	O		
OTHER REVIEW		19	EVAL. CODE											
		20												

SIGNATURE OF REVIEWER: [signature]

DATE: 1/24/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE	NAME OF FOREIGN LABORATORY
1-24-03	Government Food Region Ringsted Residue Laboratory

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Danish Veterinary and Food Administration	Ringssted, Denmark	Sondervang 4 . DK-4100 Ringsted

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Oto Urban	Dr. Arne Kongsted, M.Sc Inga Orntoft

RESIDUE	ITEM	COMMENTS

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Hjorring afdeling Wenbovej 11-9800 Hjorring	01 - 16 - 03	13	Denmark
5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT	
Dr. Oto Urban		[X] ON-SITE AUDIT	[ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK – Est. 13 1-16-03

10/46. Condensation was observed over a conveyor belt in the boning room. The establishment took immediate corrective action.

46/56 Plastic containers designated for edible purposes were used for inedible product. DVFA ordered immediate corrective action.

10/45/56 Inadequately cleaned knives and large plastic containers were observed before the start of operations in production areas. This was corrected by the establishment officials before operations were allowed to begin. This was in violation of EC Directive 64/433.

11/39/56 Flaking paint and rust was observed on rails in product traffic areas in the boning room. This was scheduled for correction by the establishment officials.

10/11. Grease from rails was observed on several carcasses. DVFA ordered immediate corrective action.

11/39/56 Rusty rails and flaking paint was observed over the product in one of the trimming coolers; corrective actions by the establishment officials were not immediate.

19. No verification of the monitoring of critical limits was performed.

The DVFA officials A Notice of Intent to Delist if the deficiencies identified were not addressed and corrected within 30 days.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
1/16/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Langbro 7. Blans 6400 Sonderborg	01 - 29 - 03	14	Denmark
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Oto Urban	[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK - Est. 14 1-29-03

11 Pieces of meat scraps and fat were found on product-contact equipment (meat hangers and conveyor belts) before the start of operations. The establishment officials took corrective actions.

19 Critical limits were monitored as required, but the verification procedures were not adequately performed. DVFA ordered prompt correction.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

1-29-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Arhus Slaugtehus A/S Jaegergardsgade 152-154 8000 Arhus C	01 - 23 - 03	34	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	X
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	X
42. Plumbing and Sewage	X
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	X
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK Est. 34 1-23-03

10/46. Condensation was observed over exposed product and exposed product traffic areas (receiving room, cooler). This was corrected by the establishment officials.

15. Many critical limits were not defined in the written HACCP plan (basic non-compliance with HACCP requirements).

15/20. The description of corrective actions, to be taken in the event that critical limits are exceeded, was inadequate (basic non-compliance with HACCP requirements). Inadequate development of the HACCP program was one of the deficiencies identified during the previous FSIS audit of this establishment.

19. No verification of the monitoring of critical limits was written in the HACCP plan or performed (basic and implementation non-compliance with HACCP requirements).

18. Fecal contamination was observed on a carcass in a cooler and on tails that passed final inspection and had been removed. Fecal contamination on product that had passed final inspection was a repeat finding from the previous FSIS audit of this establishment. These deficiencies were corrected after the auditor pointed them out.

27. A statistical process control to evaluate the results of testing for generic *E. coli* had still not been properly implemented and documented (this was a repeat finding).

40. Light was inadequate in the suspect pen.

41/42. A foul sewer odor was coming from a drain in the shipping room. The auditor was told that it was expected to be corrected after April 2003.

46/56 Beef carcasses were contacting the boot guard of the eviscerator's platform; the platform was not being sanitized after the contact. The eviscerator was frequently observed to stand on the boot guard, adding to the contamination. This did not meet the requirements of EC Directive 64/433. Similar common-contact was one of the deficiencies identified during the previous FSIS audit of this establishment. DVFA officials ordered correction.

46/56 Dirty hooks were observed in the product receiving room and there was not enough water in the sterilizer in the re-inspection room. This did not meet the requirements of EC Directive 64/433. These deficiencies were corrected immediately by the company officials.

46/54 The animals presented for slaughter were extremely dirty, with large clumps of dry feces and straw attached to their hides, contributing to the sanitary dressing problems.

55. Some large bruises that had not been trimmed were observed on carcasses in the cooler.

Note: This establishment had been found unacceptable during the previous FSIS audit on February 18, 2002, and had been recently re-listed on the basis of assurances provided to FSIS by DVFA that all the deficiencies identified had been addressed and corrected. Following this 2003 audit, the DVFA officials agreed to remove this establishment once more from the list of establishments eligible to export to the U.S., as of the start of operations on the day of the audit.

61. NAME OF AUDITOR		62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban		1-23-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown-Oksekodsdivisionen, Aalborg, Aalborg Ost or Dane Beef, Aalborg Ost	01 - 10 - 03	62	Denmark

5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT
Dr. Oto Urban	[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60 Observation of the Establishment

DENMARK - Est. 62 1-10-03

46/56 (a) The power cord to a compressed-air-powered skinning tool was long enough to contact the floor during the skinning operation, with a potential to cause cross-contamination (it was not observed actually to contact the product). This deficiency was corrected immediately by the establishment officials. (b) The bleeder failed to sterilize his knife, after opening the skin and before opening the major blood vessels, the first time he was observed. This did not meet the requirements of EC Directive 64/433. Danish officials took immediate corrective actions and the deficiency was not repeated.

40 Light in the suspect pen was inadequate.

55 The conveyor speed of carcasses was slightly faster than that of heads and viscera trays, bringing into some question whether all parts of a carcass could be easily identified, should the need arise. Management stated that they could reliably identify all parts of any carcass during the slaughter process; inspection officials supported this statement, but agreed that the system could be better, and agreed to improve the identification of parts with carcasses.

61. NAME OF AUDITOR		62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban		1/10/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hjorring Frysehus ApS Hjorring	01 – 15 - 03	165	Denmark
5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT	
Dr. Oto Urban		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK - Est. 165 1-15-03

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

1-15-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hadersley Fryselus Findlandvej 10 6100 Hadersley	01 - 31 - 03	176	Denmark
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Oto Urban	[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK - Est. 176 1-31-03

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

1-31-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Padborg Frysehus Industrivej 10 6330 Padborg	01 – 30 - 03	178	Denmark
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Oto Urban	[X] ON-SITE AUDIT	[ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK – Est. 178 1-30-03

13. The descriptions of both pre-operational and operational findings were inadequate, although corrective actions were adequately described. This was scheduled to be corrected.

38/39/56. There were obvious holes under several doors in the cooler area. This deficiency was scheduled for correction by the establishment management. This was in violation of EC Directive 64/433.

61. NAME OF AUDITOR		62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban		1-30-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agri-Norcold A/S, Lilledybet 6, 9220 Aalborg Ost	01-15-03	196	Denmark
5. NAME OF AUDITOR(S)		**6. TYPE OF AUDIT**	
Dr. Oto Urban		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	X
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	X
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK – Est. 196 1-15-03

12. The descriptions of the daily sanitation findings and corrective actions were inadequate

13. The daily sanitation documentation did not reflect the conditions observed during the audit of this cold store (dirty floor, pieces of broken wood). The establishment management agreed to improve the documentation.

38. An open door (possible entrance for rodents) was observed in the shipping area. This was corrected immediately.

39/46. Grossly excessive snow and ice were present in one area of the freezer. The establishment scheduled corrective action.

44. Housekeeping was very poor in the dressing room: cabinets were covered with dust, and dirty clothes and shoes were stored together with clean work clothes. DVFA ordered prompt corrective actions.

47. Employees' helmets in the shipping area were covered with thick dust. The establishment scheduled corrective action.

56/38/39/44/46/47 EC Directive 64/433.

This establishment was issued a Notice of Intent to Delist by the DVFA officials if the deficiencies identified are not corrected within 30 days.

61. NAME OF AUDITOR		62. AUDITOR SIGNATURE AND DATE
Oto Urban	for	1-15-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigoscandia A/S Finlandkaj 2 DK-5000 Odense C	02 - 05 - 03	198	Denmark
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Oto Urban	[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific evert occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK - Est.198 2-5-03

13. The descriptions of pre-operational and operational sanitation findings was not adequately detailed. DVFA ordered corrective action.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

2-5-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danexport A/S Kornvej 1 Hobro	01 - 17 - 03	236	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK - Est. 236 1-17-03

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

1-17-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Nordre Havnevej 1 6000 Kolding	01 – 28 - 03	315	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan.	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK - Est. 315 1-28-03

39/56 Rat activity outside the establishment was frequently described in the documentation (there was no sign I of activity in the establishment). Establishment officials stated that the presence of mice was not considered an important problem, only the presence of rats. This misinterpretation of the requirements was corrected immediately.

46/56 Plastic containers designated for edible purposes was used for inedible product (livers contacting the floor), in violation of EC Directive 64/433. This was corrected by the establishment officials.

61. NAME OF AUDITOR		62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban		1-28-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agri-Norcold Skivevej 43 Dk-9500 Hobro	01 - 20 - 03	377	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	X
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK - Est. 377 1-20-03

13 The descriptions of daily sanitation findings did not go into adequate detail. DGAL ordered prompt correction by the establishment officials.

39/56 There were obvious holes under the main doors in the shipping area. There was documentation of rodent activity outside the establishment. This did not met the requirements of EC Directive 64/433. This was scheduled for correction by the establishment management.

44 Dirty street clothes were mixed with clean work clothes in the dressing room. This was corrected by the establishment officials.

61. NAME OF AUDITOR		62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban		1-20-03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tulip Food Company Fedtsmeltiriet 8900 Randers	01 – 22 - 03	4533	Denmark
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Oto Urban	X ON-SITE AUDIT	DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan.	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

DENMARK - Est. 4533 1-22-03

13 Preventive measures were not included in the daily SSOP records. This was scheduled for correction by the establishment officials.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

1-22-03

Ministeriet for Fødevarer, Landbrug og Fiskeri
Fødevaredirektoratet
Danish Veterinary and Food Administration

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C.
20250
USA
att.: Sally Stratmoen, Acting Director
International Equivalence Staff
Office of International Affairs

Date: 1 August 2003
Our ref.: HP
File: 2002-20-7515-00017
Please note when replying

Sent by fax
202-690-4040
3 pages incl. this page.

Re.: Comments on draft audit report.

This is in response to letter of May 19, 2003 from FSIS, enclosed the draft audit report for the on-site audit of Denmarks meat inspection system, conducted by FSIS from January 6, 2003 through February 5, 2003.

By the letter Denmark was invited to provide comments regarding the information in the report within 60 days of the receipt of the letter. The Danish Veterinary and Food Administration (DVFA) hereby wish to forward the following comments:

Page 5, section 2:
"... the following sites were visited:... four swine slaughter establishments..."

Comment: two cattle and two swine slaughter establishments were visited.

Page 7, section 5:
"The last two audits of Denmarks inspection system have shown serious problems"

Comment: DVFA is of the opinion that it is concluded in the audit reports for the last two years, that Denmark has a well functioning inspection system in compliance with the USA requirements.

OIA/1599
BW 8/1 03

Mørkhøj Bygade 19
DK-2860 Søborg

Tlf: +45 33 95 60 00
Fax: +45 33 95 60 01

Internet: www.foedevaredirektoratet.dk
e-post: foedevaredirektoratet@fdir.dk

Page 8, section 6.2.1:
"Within the Food Control Department of each RVFCA were the Chief Veterinarians, who served as field supervisors over the resident veterinarians and inspectors within one or more certified establishments"

Comment: DVFA agree that the Chief Veterinarians serves as field supervisors over the resident veterinarians, meaning that they are leaders for the veterinarians. However the monthly reviews are not in all cases carried out by Chief Veterinarians. The reviews can also be carried out by other specialised auditors in the RVFCA's.

Page 8, section 6.2.2:
"Two establishments required a 30-day letter from the CCA"

Comment: Please see the below mentioned comments on section 7.

Page 8, section 6.2.3:
"Supervision of inspectors in the certified establishments needs to be improved"

Comment: DVFA has revised the instructions to the RVFCAs on how to carry out the monthly reviews, with a view to improve the follow-up procedures in connection with findings of deficiencies in the certified establishments.
Please also refer to letter from DVFA of 19 June 2003 describing the plans for a new audit unit in DVFA.

Page 9, section 6.2.4:
"In one establishment, zero tolerance for fecal contamination was not enforced"

Comment: DVFA agree that a deficiency concerning fecal contamination was found in one establishment. This, however, does not mean that the zero tolerance for fecal contamination was not enforced. The zero tolerance is enforced in all establishments.

Page 10, section 7:
"Two establishments received a "30-day letters" (notification in writing that corrective actions must be implemented within 30 days)"

Comment:
The follow-up on the 2 companies which received a Notice of Intent to Delist, has been as follows:

Est. No. 196, Agri-Norcold, Aalborg, date of audit 15 January 2003:

- The audit findings were informed to the company by letter of 28 January 2003 from RVFCA-Aalborg. The Company was ordered to write a response letter before 10 February 2003, including an action plan for correcting the deficiencies, specially the SSOP and the HACCP programme,
- By letter of 6 February 2003 the company responded as requested
- RVFCA- Aalborg carried out a new audit on 14 February 2003. It was concluded, that the company had sufficiently corrected the deficiencies, and had improved the SSOP and HACCP programmes sufficiently.

Est. No. 13, Danish Crown, Hjørring, date of audit 16 January 2003:

- The audit findings were informed to the company by letter of 20 January 2003 from RVFCA-Aalborg. The Company was ordered to write a response letter before 6 February 2003, including an action plan for correcting the deficiencies, specially the SSOP programme and the own-check programme, as regards maintenance.
- By letter of 30 January 2003 the company responded as requested
- RVFCA- Aalborg carried out a new audit on 13 February 2003. It was concluded, that the company had sufficiently corrected the deficiencies, and had sufficiently improved the SSOP and own-check programme.

Page 15, section 13.2, subsection 1:
"Sample verification is performed upon request by the DVFA where the official veterinarian collects samples and the DVFA analyzes the sample"

Comment: Salmonella verification samples are taken by the RVFCAs once every week in each slaughter establishment, as a routine. These samples are analysed at the RVFCA laboratories.

Yours Sincerely

Dr. Birgitte Povlsen
Senior Veterinary Officer
Head of Import-Export Division
Food Department